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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,919

09/29/2006

Kenji Mori

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EXAMINER

BOSWORTH, KAMI A

ART UNIT

PAPER NUMBER

4177

NOTIFICATION DATE

DELIVERY MODE

07/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/594,919	Applicant(s) MORI ET AL.	
	Examiner KAMI A. BOSWORTH	Art Unit 4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 7 and 9 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 10 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/29/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character not mentioned in the description: 72 (Fig 5). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 2 and 6 are objected to because of the following informalities: In claims 2 and 6, "the distal end opening face" lacks proper antecedent basis; it is suggested the term "the" be replaced with the term "a". Appropriate correction is required.

3. Claims 4 and 8 are objected to because of the following informalities: In claims 4 and 8, "the distal end side" lacks proper antecedent basis; it is suggested the term "the" be replaced with the term "a". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 4, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Re claim 2, the applicant claims "an engagement hole ... constituting a cut piece"; however, it is unclear if this "engagement hole" and "cut piece" are an embodiment of the "engagement means" of claim 1 or whether they are a separate feature of the claimed invention.

7. Re claims 4 and 8, the applicant claims "a distal end opening face"; however, it is unclear if this "distal end opening face" is intended to be the same distal end opening face of claims 2 and 6, respectively, or whether it is a separate feature of the claimed invention.

8. Re claim 10, the claim provides for the use of the intra-aortic balloon pumping method, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As in claim 1, "The aorta" cannot be claimed in an application as it is a human body part. It is suggested that the applicant change line 2 of claim 1 to read, "a balloon part adapted to be inserted inside the aorta...".

11. Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

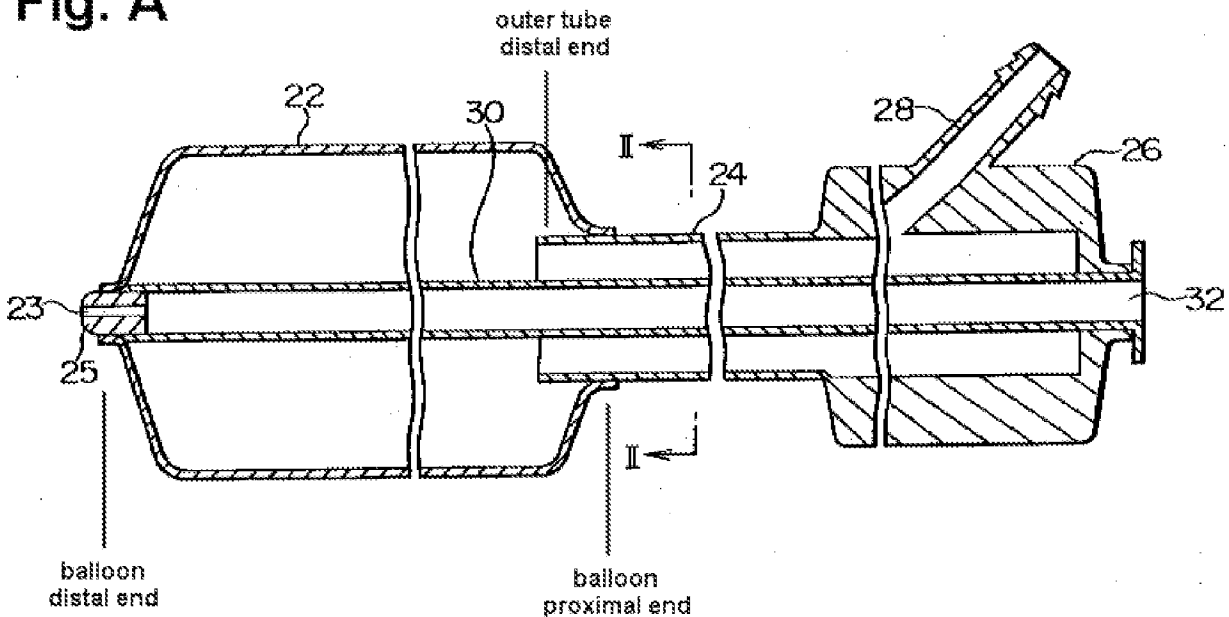
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Miyata et al. (US Pat 5,711,754).

15. Re claim 1, Miyata et al. disclose an intra-aortic balloon catheter 20 (Fig 1) comprising: a balloon part 22 (Fig 1) adapted to be inserted inside the aorta and inflating and deflating to assist the heart function (Col 2, Line 66 - Col 3, Line 1), an outer tube 24 (Fig 1) with a distal end (seen in Fig A below) connected to a proximal end (seen in Fig A below) of said balloon part (Col 4, Lines 66-67) to introduce and guide out pressurized fluid inside of said balloon part (Col 4 Line 67 – Col 5, Line 3), and an inner tube 30 (Fig 1) to which a distal end (seen in Fig A below) of said balloon part is connected (Col 4, Lines 53-55) and extending through the insides of said balloon part and said outer tube in the axial direction (Col 4, Lines 55-57) and wherein said inner tube is fused or adhered with the inside wall of said outer tube (Col 5, Lines 36-39), and an engagement means (adhesion; Col 5, Lines 36-39) engages said inner tube with the inside wall of said outer tube at the distal end of said outer tube. Miyata et al. does not explicitly disclose that the inner tube is fused or adhered with the inside wall of said outer tube over a length of 50% or greater of the total length from the distal end of the outer tube; however, as the inner tube and outer tube are affixed to one another by integral formation (Col 5, Lines 36-39), the tubes are inherently adhered over their entire length. In the alternative, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to affix the inner tube and the outer tube to one another over a length of 50% or greater of the total length of the outer tube for the purpose of ensuring a lasting affixation between the

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inner and outer tubes.

Fig. A

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al. in view of Schock (US Pat 6,830,559).

18. Re claim 5, Miyata et al. disclose all the claimed features except wherein the inner tube increases in diameter distal to the engagement means. Schock, however, teaches that the outside diameter of an inner tube 123 (Fig 4) positioned at the distal end side 132 (Fig 4) from said engagement means (embedding in co-lumen tube 118; Fig 2A; Col 4, Lines 64-66) is larger than the outside diameter of said inner tube positioned at the proximal end side 130 (Fig 4) from said engagement means (Col 5, Lines 4-9) for the purpose of assuring adequate stiffness of the inner tube to resist excessive movement during pumping. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Miyata et al. to include an inner tube having a larger diameter distal to the engagement means, as taught by Schock, for the purpose of assuring adequate stiffness of the inner tube to resist excessive movement during pumping.

Allowable Subject Matter

19. Claims 6, 7, and 9 are allowed.
20. Claims 2-4, 8, and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and 35 U.S.C. 101 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Janacek (US Pat 5,667,493) and Miraki (US Pat 5,389,087) disclose catheters having an engagement hole enabling insertion of an inner tube for engagement with an outer tube. Dirks et al. (US Pat 5,846,246) and Venturelli (US Pat

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6,635,029) disclose catheters having a cut piece enabling insertion of an inner tube for engagement with an outer tube. Twardowski et al. (US Pat 5,569,182), Auth et al. (US Pat 5,827,229), and Miraki (US Pat 5,387,193) disclose catheters having an opening face that forms an acute angle with a longitudinal axis of the catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 8:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang D. Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 4177

/Quang D. Thanh/
Supervisory Patent Examiner, Art
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